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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Docket No. 99N-4783
Administrative Practices and Procedures; Good Guidance Practices

27 April 2000

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule entitled "Administrative Practices and Procedures; Good Guidance Practices" published in the Federal Register on February 14, 2000. Outlined below are Genzyme's comments for your consideration.

1. The proposal to create several mechanisms for early input is excellent and appreciated. Users of guidance documents are readily able to determine areas needing further development or clarification. It is imperative that FDA solicits input as soon as possible for guidance documents to ensure user adequacy.
2. §10.115(g)(2) states that FDA will not seek public comment "... before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate." We recognize the need for the agency to be able act unilaterally under the circumstances defined in the supplementary information section (V)(D)(1). However, implementing policy without notice seems unfair. Since most submissions require at least 30 days to prepare, we suggest a 30 day grace period for Level 1 guidance documents implemented without public participation.

Genzyme appreciates the opportunity to comment on this draft guidance. Please contact me at (617) 252-7757 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

Alison Lawton
Senior Vice President
Regulatory Affairs

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